

REMARKS

The Office Action of January 27, 2003 has been received and reviewed. Claims 1-19 and 24-28 are currently pending in the application. All claims stand rejected. Claims 1, 3-9, 11, 13, 14 and 17-19 have been amended, claims 2, 10, 12 and 24-28 have been canceled and new claims 29-34 have been added as set forth herein. All amendments and cancellations are made without prejudice or disclaimer. Reconsideration is respectfully requested.

Priority Document

The priority document was forwarded to the Office on April 16, 2003.

Drawings

Since the drawings are acceptable for examination purposes, applicants will address changes to the drawings once a notice of allowance is received.

Sequence Compliance

The specification has been amended to include sequence identifiers where appropriate.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-19 and 24-28

Claims 1-19 and 24-28 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Claims 2, 10, 12 and 24-28 have been canceled rendering the rejections thereof moot. At least partially in view of the amendments to claims 1, 3, 4 and 11, applicants respectfully request that the rejections be withdrawn.

Specifically, it was thought the phrase "SsgA-activity" was not clear. Although applicants do not agree that the pending claims are indefinite, to expedite prosecution of the application, independent claim 1 has been amended to recite "lacking detectable endogenous SsgA" and the term "activity" has been removed from claim 1. Dependent claims 3, 4 and 11

have been amended to reflect the amendment to claim 1. Accordingly, reconsideration and withdrawal of the indefinite rejections of claims 1, 3-9, 11 and 13-19 are requested.

Claims 1 and 3-19

Claims 1 and 3-19 further stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite since the phrases “reduced branching and fragment septation” and “having at least the sequence” of claim 1 were thought to be unclear. Claims 10 and 12 have been canceled rendering the rejections thereof moot.

The phrase “reduced branching and fragment septation” has been removed from claim 1 and the phrase “having at least the sequence” has been amended to recite “comprising the sequence.” Accordingly, claims 1, 3-9, 11 and 13-19 should be definite and reconsideration and withdrawal of the indefiniteness rejections are requested.

Claims 1, 2 and 3-19

Claims 1, 2 and 3-19 were also rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for reciting the phrase “significant endogenous ssgA activity.” Claims 2, 10 and 12 have been canceled rendering the rejections thereof moot.

The phrase “significant endogenous ssgA activity” has been amended to recite “detectable endogenous SsgA” and should render claims 1, 3-9, 11 and 13-19 definite. Reconsideration and withdrawal of the indefinite rejections of claims 1, 3-9, 11 and 13-19 are requested.

Claims 2 and 24-28

Claims 2 and 24-28 were further rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Claims 2 and 24-28 have been canceled rendering the rejections thereof moot.

Claims 3 and 24

Claims 3 and 24 also stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for lacking antecedent basis for the phrase “said additional SsgA activity.” With further regard to claim 3, it was asserted that the phrase “additional SsgA activity” was not clear as to how the SsgA activity can be additional. Claim 24 has been canceled rendering the rejection thereof moot.

Claim 3 has been amended to recite “said heterologous SsgA” wherein the term “additional” has been removed. As amended, proper antecedent basis for claim 3 exists in claim 1. Reconsideration and withdrawal of the indefiniteness rejection of claim 3 are requested.

Claims 3-19

Claims 3-19 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite since claims 3, 8 and 9 recite the phrase “additional genetic information.” Claims 2, 10 and 12 have been canceled rendering the rejections thereof moot.

Specifically, it was thought that the phrase “additional genetic information” was not clear. In accordance with the suggestion of the Examiner, the phrase “additional genetic information” has been replaced with the term “DNA” in claims 3, 4, 8 and 9. Reconsideration and withdrawal of the indefiniteness rejections of claims 3-9, 11 and 13-19 are requested.

Claims 5-7 and 26-28

Claims 5-7 and 26-28 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for reciting the phrase “derived from an actinomycete” and “derived from streptomycete.” Claims 26-28 have been canceled rendering the rejections thereof moot.

The term “derived” has been deleted claims 5 and 6 and the claims 5-6 have been amended to recite in part “wherein said ssgA gene is of a [actinomycete or streptomycete]

origin,” respectively. Reconsideration and withdrawal of the indefiniteness rejections of claims 5-7 are, thus, requested.

Claim 10

Claim 10 was further rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Claim 10 has been canceled rendering the rejection thereof moot.

Claim 14

Claim 14 was rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for reciting the phrase “useful product” since it was thought to be unclear what the useful product may be.

It was thought that no specific definition was disclosed in the specification for a “useful product.” Applicants direct the Examiner to page 6, lines 24-35 and page 7, lines 1-8 for a definition and examples of the useful product. Reconsideration and withdrawal of the indefinite rejection of claim 14 are requested.

Claims 24-28

Claims 24-28 were rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Claims 24-28 have been canceled rendering the rejections thereof moot.

Rejections under 35 U.S.C. § 112, first paragraph

Enablement

Claims 1-11, 14-19 and 24-28

Claims 1-11, 14-19 and 24-28 were rejected under 35 U.S.C. § 112, first paragraph, since the specification assertedly lacks enablement for a method of rendering any or all filamentous bacteria to exhibit reduced branching and fragment septation and enhanced fragmentation using DNA of SEQ ID NO: 1. Claims 2, 10 and 24-28 have been canceled rendering the rejections thereof moot. At least partially in view of the amendments to claim 1, applicants respectfully traverse the rejections.

Specifically, it was thought that “the specification, while being enabling for a method of producing a filamentous *Streptomyces* bacterium exhibiting reduced branching and fragment septation and enhanced fragmentation using DNA with SEQ ID NO: 1, does not reasonably provide enablement for such a method for rendering any or all filamentous bacteria to exhibit reduced branching and fragment septation and enhanced fragmentation using DNA with SEQ ID NO: 1.” (Office Action, page 8). Although applicants do not agree that the claims are not fully enabled, to expedite prosecution of the pending application, claim 1 has been amended to recite in part “providing a filamentous Actinomycete bacterium.”

“As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. (M.P.E.P. § 2164.01(a), *citing In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA)). Not only have the applicants disclosed one working example, they have, in fact, disclosed that SEQ ID NO: 1 reduces branching and increases fragmentation in the Actinomycetes including *S. coelicolor*, *S. lividans*, *S. clavuligerus* and *Sacch. erithraea*. (See, Specification, page 6 lines 6-35 and page 7, lines 1-8). Since the applicants have shown that SEQ ID NO: 1 reduces branching and increases fragmentation in four different species of Actinomycetes, the claims should be enabled. Accordingly, reconsideration and withdrawal of the enablement rejections of claims 1, 3-9, 11 and 14-19 are requested.

Claims 4-19

Claims 4-19 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking enablement for any DNA comprising *ssgA* gene, a derivative or fragment thereof. Claims 10 and 12 have been canceled rendering the rejections thereof moot. At least partially in view of the amendments to claims 4, 8 and 9, applicants respectfully traverse the rejections.

It was thought that the specification does not reasonably provide enablement for any DNA comprising a *ssgA* gene, a derivative or fragment thereof. Applicants traverse the rejections because it is known that some modifications can be made to an original nucleic acid, wherein a modified nucleic acid will encode the same protein as the original nucleic acid or the modified nucleic acid will encode a protein having the same function as the protein encoded for

by the original nucleic acid. For instance, the known degeneracy and wobble hypothesis pertaining to the genetic code results in the fact that some nucleotide substitutions in a nucleic acid will result in a modified nucleic acid that produces the same protein. Thus, applicants do not disclaim functional equivalents of the claimed sequences by the amendments to the claims made herein.

Although applicants do not agree that the claims are not enabled, applicants have removed the phrase “or a derivative or fragment thereof encoding similar SsgA activity” from claim 4 to expedite prosecution of the application. Accordingly, applicants respectfully request reconsideration and withdrawal of the enablement rejections of claims 4-9, 11 and 13-19.

Written Description

Claims 3-19 and 24-28

Claims 3-19 and 24-28 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. Claims 10, 12 and 24-28 have been canceled rendering the rejections thereof moot. Partially in view of the amendments to the claims, applicants respectfully traverse the rejections.

Specifically, it was through that the specification does not contain any disclosure of the structure and function of all such “additional genetic information” comprising DNA sequences. (See, Office Action, page 10). Claim 3 has been amended to recite in part “wherein said heterologous SsgA is provided by transfecting or transforming said filamentous Actinomycete bacterium with DNA encoding said SsgA.” The specification supports amended claim 3 by stating “the activity is provided by transfecting or transforming said filamentous bacterium with additional genetic information ... the genetic information encoding the additional SsgA activity is integrated into the host cell genome ... typically the genetic information will be in the form of DNA.” (Specification, page 5, lines 4-6 and 31-33). Accordingly, one of skill in the art would reasonably conclude that the inventors had possession of the claimed invention.

Accordingly, reconsideration and withdrawal of the written description rejections of claims 3-9, 11 and 13-19 are requested.

Claims 4-19

Claims 4-19 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. Claims 10 and 12 have been canceled rendering the rejections thereof moot.

Specifically, it was thought that that the specification does not include any disclosure of the structure of “derivatives and fragments” comprising DNA sequences. To expedite prosecution, applicants have removed the phrase “or a derivative or fragment thereof encoding similar SsgA activity.” Accordingly, one of ordinary skill in the art would reasonably conclude that applicants had possession of the claimed invention.

Reconsideration and withdrawal of the written description rejections of claims 4-9, 11 and 13-19 are requested.

Rejections under 35 U.S.C. § 102

Claims 1-15 and 24-28 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Kawamoto et al. Claims 2, 10, 12 and 24-28 have been canceled rendering the rejections thereof moot. Applicants respectfully traverse the rejections as hereinafter set forth.

Kawamoto et al. does not anticipate claim 1 since Kawamoto et al. does not disclose each and every element of claim 1. Claim 1 recites in part “providing a filamentous Actinomycete bacterium, said filamentous bacterium lacking detectable endogenous SsgA, with the capability of having or expressing heterologous SsgA, which heterologous SsgA, in *Streptomyces griseus*, is encoded by an ssgA gene comprising [SEQ ID NO: 1].” Kawamoto et al. does not disclose providing a filamentous Actinomycete bacterium **lacking detectable endogenous SsgA** as required to anticipate claim 1.

Accordingly, applicants request reconsideration and withdrawal of the anticipation rejection of claim 1 and claims 3-9, 11 and 13-15 depending therefrom.

Rejections under 35 U.S.C. § 103

Claims 16-19 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Kawamoto et al. as applied to claims 1-15 and 24-28 above, and further in view of the common knowledge in the art for making recombinant heterologous proteins. Applicants respectfully traverse the rejections as hereinafter set forth.

Claims 16-19 are non-obvious, at the very least, as directly or indirectly depending from non-obvious independent claim 1. (*See, In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Thus, reconsideration and withdrawal of the obviousness rejections of claims 16-19 are requested.

New claims 29-34

New claims 29-34 have been added to reflect the fact that some modifications can be made to an original nucleic acid, wherein a modified nucleic acid will encode the same protein as the original nucleic acid or the modified nucleic acid will encode a protein having the same function as the protein encoded for by the original nucleic acid. For instance, the known degeneracy and wobble hypothesis pertaining to the genetic code results in the fact that some nucleotide substitutions in a nucleic acid will result in a modified nucleic acid that produces the same protein.

CONCLUSION

In view of the amendments and remarks presented herein, applicants respectfully submit that the amended claims define patentable subject matter. If questions should remain after consideration of the foregoing, the Examiner is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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